REMARKS

Reconsideration of the present application, as amended, in view of the following remarks is respectfully requested. Claims 2, 3, 73-75 and 77-109 are currently pending and under consideration, of which claims 80, 81, 93 and 94 are amended. Claims 110-116 have been withdrawn from consideration and claims 1, 4-72 and 76 have been cancelled.

Applicants acknowledge and thank the Examiner for the indication in the outstanding Office Action that the arguments filed 10/15/2007 have been fully considered and are persuasive. The outstanding Action dated March 19, 2008, is a new, Non-final Action.

As an initial matter, Applicants would point out that the outstanding Office Action provides no substantive grounds for rejecting claim 75 or claim 79. Thus, a *prima facie* case for rejecting these claims has not been established, and Applicants respectfully request an indication of the allowability of these claims. If the Examiner believes there is any legitimate rationale for rejecting claim 75 or claim 79, then another office action stating such rationale is respectfully requested so the same can be considered and rebutted if appropriate.

As another initial matter, in the course of reviewing the pending claims, Applicants observed that the term "chamber" in claims 81-84 lacked proper antecedent basis in claim 80. Applicant's have amended claims 80 and 81 to provide proper antecedent basis for this term.

Of the claims that are currently pending in the present case, two are independent claims, namely, claims 73 and 94. Independent claim 73 is directed to a spinal spacer that comprises "a cylindrical bone dowel ... having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor." Independent claim 94, which is amended above for the purpose of improving its clarity, is directed to a spinal spacer that comprises "a bone graft including a chamber ... and an effective amount of an osteogenic composition including a substantially pure osteogenic factor packed within said chamber." While the subject matter of both of claims 73 and 94 involves spinal spacers that include bone and that include an osteogenic composition including a substantially pure osteogenic factor, the subject matter of these claims differ in two main respects. Because various statements in the outstanding Office Action seem to overlook the differences between

the subject matter of claims 73 and 94, these differences are discussed in the following three paragraphs.

First, the orientation of the osteogenic composition relative to the bone in the spinal spacers recited in claims 73 and 94 is different. Specifically, in claim 73, the osteogenic composition is impregnated in the bone; and in claim 94, the osteogenic composition is packed within a chamber of the bone graft. In this regard, paragraph [0018] of the present application (published version) states that:

> The osteogenic composition includes a substantially pure osteogenic factor in a pharmaceutically acceptable carrier. In one embodiment the load bearing member includes a bone graft impregnated with an osteogenic composition. In another embodiment, the osteogenic composition is packed within a chamber defined in the graft.

A person of ordinary skill in the art would readily appreciate that the term "impregnated" carries with it, for example, the connotation of absorption or soaking of the osteogenic composition into the internal portions of the bone graft, i.e., into the internal structure of the bone tissue. In contrast, the phrase "packed within a chamber" would be understood to refer, for example, to the positioning of an osteogenic composition into a space defined by the surface of the bone graft, i.e., adjacent to the bone tissue but not necessarily within the microstructure of the bone tissue. The distinction between these two orientations is further discussed in paragraph [0112] of the published application, which states that, "An osteogenic material can be applied to the spacers of this invention by packing the chamber 25, 130 with an osteogenic material 30, 148 as shown in FIGS. 32 and 47, by impregnating the graft with a solution including an osteogenic composition or by both methods combined." With regard to the disclosure of a spacer that includes an osteogenic compositions applied "by both methods," Applicants would draw the Examiner's attention to dependent claim 82, which depends indirectly from independent claim 73. Claim 82 is directed to a spinal spacer that includes a first osteogenic composition impregnated in the bone (see claim 73) and "a second osteogenic composition...packed within said chamber."

Second, the physical properties of an osteogenic compositions to be packed within a cavity or chamber are described differently in the present application than the physical properties of an osteogenic composition to be impregnated in bone, and a person of ordinary skill in the art will appreciate that these differences relate to the significantly different size of a cavity or chamber as compared to the sizes of pores and/or other microstructural spaces in the bone tissue. Specifically, an osteogenic composition to be packed in a cavity or chamber has physical properties that give it a shape-retaining quality, such as, for example, a solid or solid-like form, which enables it to remain positioned in a cavity or chamber defined by the bone graft without flowing out of the cavity or chamber under normal conditions. An osteogenic composition to be impregnated in bone tissue has physical properties that give it a more flowable or fluid-like form, which enables it to enter pores on the surface of bone tissue and become impregnated in bone tissue. The specification of the present application discusses this distinction, and identifies examples of different types of carriers that can be used in osteogenic compositions used for these distinct purposes. With regard to an osteogenic composition that is impregnated in bone, as recited in claim 73, the following excerpts from paragraph [0119] of the specification of the present application discuss examples of various types of carriers that can be used in an osteogenic composition that is impregnated in a bone dowel:

> [0119] ... The bone growth inducing composition can be introduced into the pores in any suitable manner. For example, the composition may be injected into the pores of the graft. In other embodiments, the composition is dripped onto the graft or the graft is soaked in a solution containing an effective amount of the composition to stimulate osteoinduction. In either case the pores are exposed to the composition for a period of time sufficient to allow the liquid to throughly [sic] soak the graft. The osteogenic factor, preferably a BMP, may be provided in freeze-dried form and reconstituted in a pharmaceutically acceptable liquid or gel carrier such as sterile water, physiological saline or any other suitable carrier. The carrier may be any suitable medium capable of delivering the proteins to the spacer. Preferably the medium is supplemented with a buffer solution as is known in the art. In one specific embodiment of the invention, rhBMP-2 is suspended or admixed in a carrier, such as water, saline, liquid collagen or injectable BCP. The BMP solution can be dripped into the graft or the graft can be immersed in a suitable quantity of the liquid. ...

Thus, a suitable pharmaceutically acceptable carrier for the embodiment recited in claim 73 is one that is effective to carry the substantially pure osteogenic factor into pores of the cylindrical bone dowel, such as, for example, a pharmaceutically acceptable liquid carrier.

With regard to an osteogenic composition that is packed within a chamber of a dowel, as recited in claim 94, an example of a physiologically acceptable carrier for this osteogenic composition is a solid or solid-like carrier. Paragraph [0117] of the specification of the present application discusses various examples of types of carriers that can be used in an osteogenic composition that is to be packed in the chamber:

> [0117] For packing the chambers of the spacers of the present invention, the carriers are preferably provided as a sponge 58, 30 which can be compressed into the chamber 55 (FIG. 25) or 25 (FIG. 47) or as strips or sheets which may be folded to conform to the chamber as shown in FIG. 48. Preferably, the carrier has a width and length which are each slightly greater than the width and length of the chamber. In the most preferred embodiments, the carrier is soaked with a rhBMP-2 solution and then compressed into the chamber. As shown in FIG. 47, the sponge 30 is held within the chamber 25 by the compressive forces provided by the sponge 30 against the wall 22 of the dowel 21. It may be preferable for the carrier to extend out of the openings of the chamber to facilitate contact of the osteogenic composition with the highly vascularized tissue surrounding the fusion site. The carrier can also be provided in several strips sized to fit within the chamber. The strips can be placed one against another to fill the interior. As with the folded sheet, the strips can be arranged within the spacer in several orientations. Preferably, the osteogenic material, whether provided in a sponge, a single folded sheet or in several overlapping strips, has a length corresponding to the length and width of the chamber.

Thus, a suitable pharmaceutically acceptable carrier for the embodiment recited in claim 94 is one that is effective to retain a physical shape in the cavity and hold the osteogenic composition in the cavity under normal conditions, such as, for example, a solid sponge, strip or sheet material. Paragraph [0118] of the present application also describes a biphasic calcium phosphate ceramic carrier, and states that, "Any size or shape ceramic carrier which will fit into the chambers defined in the load bearing member are contemplated." A person of

ordinary skill in the art will appreciate that these and other shape-retaining types of carriers can be used in an osteogenic composition to be packed within a cavity or chamber as recited in claim 94.

Both of independent claims 73 and 94 are rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as being unpatentable over two different combinations of references, namely: (i) University of Florida Tissue Bank, Inc. (as disclosed in applicant's own specification, para. 0012 in the PG-Pub) (hereafter "UFTB") in view of U.S. Patent No. 5,674,292 to Tucker et al. (hereafter "Tucker"), and (ii) U.S. Patent No. 5,514,180 to Heggeness et al. (hereafter "Heggeness") in view of Tucker. Each of the two independent claims is discussed separately below.

Independent claim 73

First with regard to the rejection of claim 73 over UFTB in view of Tucker, Applicants traverse this rejection and submit that the Office Action fails to establish a *prima facie* case of obviousness over the cited combination of references.

Based upon various statements in the outstanding Office Action, it appears that the term "impregnating" in claim 73 has been misunderstood. As discussed above, packing a material in a cavity does not constitute "impregnating" as that term would be understood by a person of ordinary skill in the art in view of the present specification. It is believed that none of the cited references discloses impregnating an osteogenic factor in a bone dowel. However, in its discussion of "a diaphysial cortical dowel marketed by the University of Florida Tissue Bank (hereafter "UFTB")" at the first paragraph of Page 3, the Action states that, "This dowel...is impregnated with an effective amount of a first osteogenic composition (either bone graft or bioceramic) which inevitably has osteogenic factors." In traversal, Applicants submit that the UFTB dowel is not impregnated with any osteogenic composition and, indeed, that the "bone graft or bioceramic" parenthetically referenced in the Action could not be used to impregnate a bone dowel because they do not have a suitable form for being impregnated into bone tissue, as discussed above.

The Action also asserts at the top of Page 4 that:

> At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the osteogenic factor taught by UFTB with the proteins and matrix/carrier taught by Tucker et al., and one would have been motivated to do so since UFTB suggests impregnation with an osteogenic composition (instant PG-Pub, para. 0012) and Tucker et al. suggests use of its osteogenic compositions in a marrow cavity (8:55-65).

Once again, Applicants submit that the statement in the Action that "UFTB suggests impregnation with an osteogenic composition" is in error. Packing a composition in a cavity formed in a piece of bone is not the same as impregnating the piece of bone. Tucker also fails to teach or suggest impregnating bone with an osteogenic composition, and any suggestion therein of "use of its osteogenic compositions in a marrow cavity" is not the same as impregnating bone with an osteogenic composition. Therefore, Applicants submit that even a combination of UFTB with Tucker fails to include the subject matter of claim 73 because neither reference discloses or suggests impregnating an osteogenic composition in bone. The Action therefore fails to establish a *prima facie* case of obviousness of claim 73 under 35 U.S.C §103(a) over a combination of UFTB and Tucker. Applicants submit that independent claim 73 is patentable over the cited combination of references, and respectfully requests an indication of same.

With regard to the rejection of claim 73 over Heggeness in view of Tucker, Applicants traverse this rejection and submit that the Office Action fails to establish a *prima facie* case of obviousness over this combination of references also. Neither of the cited references, nor the combined disclosures thereof, describes or suggests a "cylindrical bone dowel...having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor" as recited in claim 73. The last paragraph of page 4 of the outstanding Action makes reference to FIGS. 24 and 25 of Heggeness as disclosing "a cylindrical spinal spacer/dowel...impregnated with one or more osteogenic compositions containing one or more osteogenic factors." This statement, however, is incorrect in at least two respects. The Heggeness device depicted in FIG. 24, and described in column 11 of

Heggeness, includes an outer ring (72) that surrounds a reservoir (73) that can be packed with an "osteoinductive material...incorporated in some solid or gelatinous matrix such as hydroxyapatite or collagen, for example. The outer ring (72) may be formed of any material normally used in the manufacture of orthopedic implants, including, but not limited to, metals, metal alloys, and ceramics." (Heggeness, column 11, lines 33-39). Similarly, the Heggeness device depicted in FIG. 25, and described in column 11 of Heggeness, includes a body (81) [that] comprises at least one chamber (84) communicating between the superior surface (82) and inferior surface (83) of the device. "Contained within each chamber is at least one osteoinductive material which is preferably incorporated in some solid or gelatinous matrix such as collagen gel, for example."

Neither of the intervertebral devices depicted in FIGS. 24 and 25 of Heggeness, however, is a "cylindrical spinal spacer/dowel" as asserted in the outstanding Action. Heggeness is directed to intervertebral devices that "are designed to accommodate the defined contours (i.e. shapes) of superior and inferior endplates of vertebral bodies, particularly those in the thoracic and lumbar spinal regions." (column 6, lines 42-45). The purpose for this feature, as stated in Heggeness at column 3, lines 15-22, is that, "It is...desirable to have an intervertebral device for use in intervertebral disc space reconstruction resulting from the removal of a single disc, or a total corpectomy, that...has defined contours or shapes that are designed to accommodate the normal and predictable morphological anatomy of the vertebral endplates, resulting in significantly better stress distribution along the endplate." The devices described in Heggeness include a body, a superior surface having a fixed shape to accommodate defined contours of an inferior vertebral endplate and an inferior surface having a fixed shape to accommodate defined contours of a superior vertebral endplate. (see column 6, lines 48-55). Thus, even if the Heggeness device were modified to include bone tissue, it would still not be a "cylindrical bone dowel configured for engagement within a concave space cut in the adjacent vertebrae" as recited in claim 73, and a person of ordinary skill in the art would not make this modification to the Heggeness device in view of its clear teachings of the importance of maintaining specific superior and inferior contours that complement the contours

of the inferior endplate of one vertebra and the superior endplate of another vertebra, respectively. The modification would render the Heggeness device unsuitable for its intended purpose, that is, the purpose of providing a device having superior and inferior contours matching the contours of adjacent vertebral body endplates.

Moreover, packing an osteogenic material incorporated in a solid or gelatinous matrix into a reservoir formed by an outer ring or a body that comprises at least one chamber, as described in Heggeness, is not the same as impregnating bone with an osteogenic composition, as recited in claim 73, and the disclosure thereof does not render the subject matter of claim 73 obvious.

The Office Action states at the bottom of page 4 that Heggeness discloses a "bone graft which inherently has osteogenic factors (10:43-46)." Column 10, lines 41-48 of Heggeness states that "in certain embodiments, the body of the inventive intervertebral device may be that of other intervertebral devices, grafts, or implants, examples of which include, but are not limited to, expandable disc prostheses, allograft and autograft sections, titanium cages, graphite boxes, spiked prosthetic intervertebral implants...and ceramic spacers." There is no explanation in the Action of how this statement in Heggeness is pertinent to the subject matter of claim 73, and Applicants submit that it has no bearing on the patentability of claim 73. While it may be possible to use allograft and autograft sections in the devices described in Heggeness, for the reasons discussed above, this does not constitute a teaching or suggestion of a "cylindrical bone dowel configured for engagement with a concave space cut in the adjacent vertebrae, said bone dowel having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor" as recited in claim 73.

In view of the above, Applicant submit that the outstanding Action fails to establish a *prima facie* case of obviousness of claim 73 over the combination of Heggeness and Tucker. Applicants therefore respectfully request withdrawal of this rejection.

Independent Claim 94

Turning now to the rejection of claim 94 over UFTB in view of Tucker, Applicants traverse this rejection and submit that the Office Action fails to establish a *prima facie* case of obviousness over the cited combination of references.

The Action states at the bottom of the first paragraph of Page 3 that "UFTB does not explicitly teach a substantially pure osteogenic factor." The Action cites Tucker as describing a substantially pure osteogenic factor via incorporation by reference of U.S. Patent No. 5,013,649 to Wang et al. (hereafter "Wang"). Specifically, the Action states at the second paragraph of Page 3 that:

> Tucker et al. incorporates by reference United States Patent Number 5013649 (6:21), which teaches a method of producing purified ... recombinant human BMP-2... The BMPs taught by Tucker et al. are assumed to be substantially pure due to the incorporation of United States Patent Number 5013649..., as well as the fact that no evidence to the contrary is present in the Tucker et al. document. (emphasis in original).

In traversal, Applicants submit that the Action fails to establish a *prima facie* case of obviousness of claim 94 over this combination of references because the Action provides no legitimate rationale for "assuming" that the BMPs described in Tucker are substantially pure as stated in the Action. Applicants submit that this assumption is incorrect for at least two reasons, namely, because (i) Tucker et al. actually does not incorporate Wang by reference, and (ii) the statement in the Action that "no evidence to the contrary is present in the Tucker et al. document" is not a proper rationale for reading subject matter into the disclosure of Tucker that is not present in its disclosure.

With regard to the assertion in the Action that Tucker incorporates Wang by reference, Applicants respectfully submit that Tucker does not include the requisite language necessary to incorporate Wang by reference. 37 CFR 1.57(b) clearly requires specific language to be present in a patent specification to incorporate the disclosure of another document by reference. Specifically, 37 CFR 1.57(b) states that, "Except as provided in paragraph (a) of this section [which does not apply in the present case], an incorporation by reference must be

set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words 'incorporat(e)' and 'reference' (e.g., 'incorporate by reference'); and (2) Clearly identify the referenced patent, application, or publication."

The Tucker patent does not include the requisite "incorporate by reference" language in its citation of U.S. Patent No. 5,013,649 to Wang. Specifically, it is believed that the only citation of Wang appears at column 6, line 21 of Tucker. The full sentence including this citation is set forth below:

> Useful sequences include those comprising the C-terminus 102 amino acid sequences of DPP (from Drosophila), Vgl (from Xenopus), Vgr-1 (from mouse), the OP-1 and OP-2 proteins (see U.S. Pat. No. 5,011,691), as well as the proteins referred to as BMP2, BMP3, BMP4 (see WO88/00205, U.S. Pat. No. 5,013,649 and WO91/18098), BMP5 and BMP6 (see WO90/11366, PCT/US90/01630), and BMP8 and 9.

None of the documents cited in this sentence are incorporated by reference in Tucker because the requisite "incorporate by reference" language is not used in connection with the documents identified in this sentence. Indeed, this stands in stark contrast to other portions of Tucker where the requisite "incorporate by reference" language is used in connection with citations to other documents. (See, e.g. Tucker at column 3, lines 59-63; and column 6 lines 24-27 and lines 49-54). Because Tucker does not use the requisite language in connection with the citation to Wang, Applicants submit that Wang is not incorporated by reference in Tucker, and that reliance on the incorporation of the disclosure of Wang into Tucker in support of this rejection is improper.

In view of the above, Applicants submit that Tucker is devoid of any teaching or suggestion of using an osteogenic composition that includes a substantially pure osteogenic factor. In addition, it is believed that none of the other references of record discloses or suggests the inclusion of a substantially pure osteogenic factor in an osteogenic composition for packing in a cavity of a bone graft as set forth in claim 94.

In addition to the above, the very existence of the Wang patent supports Applicants' position that the subject matter recited in claim 94 is not obvious under 35 U.S.C. §103(a).

The Wang patent was issued in May of 1991, and yet no prior art has been identified that describes the inclusion of a substantially pure osteogenic factor in a spinal spacer as recited in claim 94. The fact that the subject matter recited in claim 94 was not disclosed in the prior art, combined with the urgent need for advancements in the related field, constitutes strong evidence that the subject matter recited in claim 94 would not have been obvious to a person of ordinary skill in the art in view of the references of record in the present case.

In view of the above, Applicants submit that the rejection of claim 94 over UFTB in view of Tucker is overcome. Applicants therefore respectfully request withdrawal of the asserted rejection of claim 94 over the combination of UFTB and Tucker.

With regard to the rejection of claim 94 over Heggeness in view of Tucker, Applicants traverse this rejection and submit that the Office Action also fails to establish a *prima facie* case of obviousness over this cited combination of references.

The Office Action acknowledges at the top of page 5 that Heggeness et al. does not explicitly teach a substantially pure osteogenic factor. The Action cites Tucker as describing a substantially pure osteogenic factor via incorporation of U.S. Patent No. 5,013,649 to Wang et al. (hereafter "Wang"), by reference. In traversal, Applicants submit that the Action fails to establish a *prima facie* case of obviousness of claim 94 over this combination of references because Tucker does not disclose the use of a substantially pure osteogenic factor. As discussed above, the Action provides no legitimate rationale for "assuming" that the BMPs described in Tucker are substantially pure, and Applicants submit that this assumption is incorrect at least because (i) Tucker et al. actually does not incorporate Wang by reference, and (ii) the statement in the Action that "no evidence to the contrary is present in the Tucker et al. document" is not a proper rationale for reading subject matter into the disclosure of Tucker that is not present in its disclosure. Moreover, as discussed above, the very existence of the Wang patent supports Applicants' position that the subject matter recited in claim 94 is not obvious under 35 U.S.C. §103(a). The Wang patent was issued in May of 1991, and yet no prior art has been identified that describes the inclusion of a substantially pure osteogenic factor in a spinal spacer as recited in claim 94. The fact that the subject matter recited in claim 94 was not

disclosed in the prior art, combined with the urgent need for advancements in the related field, constitutes strong evidence that the subject matter recited in claim 94 would not have been obvious to a person of ordinary skill in the art in view of the references of record in the present case.

In view of the above, Applicants submit that the rejection of claim 94 over Heggeness in view of Tucker is overcome. Applicants therefore respectfully request withdrawal of the asserted rejection of claim 94 over the combination of Heggeness and Tucker.

Dependent Claims

Claims 2, 3, 74-75 and 77-93 depend, either directly or indirectly, from independent claim 73; and claims 95-109 depend, either directly or indirectly, from independent claim 94. Applicants submit that these dependent claims recite patentable subject matter for at least the same reasons that the subject matter of independent claims 73 and 94 are patentable, and for other reasons. For example, Applicants submit that the Action reflects an erroneous interpretation of claim 82. Claim 82 is dependent upon claim 80, which is in turn dependent on claim 73. Claim 82 recites that "said bone dowel defines a chamber" and that the spacer further comprises "an effective amount of a second osteogenic composition to stimulate osteoinduction, said second composition packed within said chamber." Even assuming *arguendo* that the prior art were to disclose a device that includes a mixture of osteogenic factors, as suggested in the paragraph spanning pages 7 and 8 of the outstanding Action, such a disclosure still would not read on the subject matter of claim 82, which recites that the "first osteogenic composition" is impregnated in the bone dowel and the "second osteogenic composition" is packed in the chamber. Applicants submit that there is no disclosure in the references of record that would make the subject matter of claim 82 obvious. The cited art does not disclose a bone dowel having an osteogenic composition impregnated therein (as discussed above), much less a bone dowel having an osteogenic composition impregnated therein AND a second osteogenic composition positioned in a chamber defined in the dowel. Applicants therefore submit that the Action fails to establish a *prima facie* case of

obviousness of claim 82 for this further reason. Applicants respectfully request an indication that claim 82 is allowed.

Dependent claims 107-109 are rejected in the outstanding Action over Heggeness in view of Tucker and further in view of U.S. Patent No. 4,877,020 to Vich; however, the Action does not identify any specific disclosures in the cited references that relate to the subject matter recited in claims 107-109. Claim 107 recites a spinal spacer as set forth in claim 94 that comprises an outer surface defining a thread, wherein the thread has a flat crest having a width of between about 0.020 inches and about 0.030 inches. Claim 108 recites a spinal spacer as set forth in claim 94 that comprises an outer surface defining a thread, wherein the thread has a leading flank and a trailing flanks defining an angle therebetween of between about 50 degrees and about 70 degrees. Claim 109 recites a spinal spacer as set forth in claim 94 that comprises an outer surface defining a thread, wherein the thread has a height between about 0.030 inches and about 0.045 inches. Rather than identifying any pertinent information in the cited references, the Action asserts that "it would have been obvious to a person having ordinary skill in the art to optimize the threads to the specific height, width and angles claimed, and one would have been motivated to do so in order to adjust the entire implant size to fit the anatomy of a specific patient or to simply test for the optimal dimensions during routine experimentation." Applicants submit that the thread features recited in claims 107-109 are not merely matters of "implant size" as suggested in the Action. A person of ordinary skill in the art would not modify the thread features of a prior art device "in order to adjust the entire implant size to fit the anatomy of a specific patient," and the prior art of record includes no teaching or suggestion that would motivate a person of ordinary skill in the art to modify thread features of a prior art device "to simply test for the optimal dimensions during routine experimentation" as asserted in the Action. Because the recited features are not disclosed in the prior art, and would not have been obvious to a person skilled in the art, Applicants submit that the Action fails to establish a *prima facie* case of obviousness of the subject matter recited in claims 107-109.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 107-109 under 35 U.S.C. § 103(a) as being unpatentable over this combination of references.

Withdrawn claims

Claims 110-116 were previously withdrawn from consideration on the grounds that they are drawn to a nonelected species and that there is no allowable generic or linking claim. Applicants respectfully request that claims 110-116 be reinstated and allowed on the basis that independent claim 94 is allowable.

Miscellaneous

Applicants reserve the right to present evidence and/or arguments in the record of this case to establish that the "University of Florida Tissue Bank, Inc. (as disclosed in applicant's own specification, para. 0012 in the PG-Pub))" is not prior art. While such a showing is not believed to be necessary to overcome the rejections asserted in the outstanding Action, Applicants do not acquiesce in the citation of paragraph [0012] of its own specification as a prior art reference. Applicants submit that this paragraph is not an admission of prior art.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the rejections asserted in the outstanding Action are overcome. Accordingly, reconsideration leading to withdraw of all the rejections under 35 U.S.C. § 103(a) and allowance of this application, as amended, containing claims 2, 3, 73-75 and 77-116 are respectfully requested.

Applicants again acknowledge and thank the Examiner for the indication in the outstanding Action that claims 83 and 84 recite allowable subject matter. The Action states that these claims are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. For the reasons stated hereinabove, Applicants submit that the base claim and the intervening claims are also in condition for allowance, and that this objection to claims 83 and 84 is therefore moot. Withdrawal of this objection is therefore respectfully requested.

If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same. Nothing in this document is intended to be an admission that any of the cited references qualifies as prior art or that the arguments in support of patentability presented herein are the only reasons that the claims are in condition for allowance. Rather, Applicants expressly reserve the right to make showings at a later time to remove/disqualify one or more references from the prior art, if appropriate, and/or to present additional arguments in favor or patentability of the pending claims over the cited references.

Respectfully submitted,

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